K080196

SEP - 5 2008

4 510(k) Summary

In accordance with the requirements addressed by the Safe Medical Devices Act of 1990, this Attachment provides the 510(k) Summary of Safety and Effectiveness information to support the determination of substantial equivalence to currently-marketed predicate devices.

A Certification is also included herein.

510(k) Summary/Statement Certification

Re: 510(k) Premarket Notification: z3D Contrast Acuity

CHECK ONLY ONE:

X 1. 510(k) Summary. Attached is a summary of safety and effectiveness information upon which an equivalence determination could be based.

____ 2. 510(k) Statement. I certify that in my capacity as

Chief Executive Officer

of Clario Medical Imaging, Inc. (company)

I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Chris Wood

CEO

Date

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.87 (h).

1. Identification of Submitter:

Submitter:	Clario Medical Imaging, Inc.
Address:	1924 1st Avenue, Suite 4W Seattle, WA 98101
Phone:	206-448-2212
Fax:	206-441-3226
Contact:	Chris Wood
Title:	Chief Executive Officer
Phone:	206-448-2212
Fax:	206-441-3226

Date Prepared:

2. Identification of Product:

Trade Name:	z3D Contrast Acuity
Common Name:	Picture Archiving and Communications System
Regulation Number:	892.2050
Classification Name:	Radiological Image Processing System
Product Cone:	90-LLZ
Regulatory Class:	Class II
Manufacturer:	Clario Medical Imaging, Inc. 1924 1st Avenue, Suite 4W Seattle, WA 98101

3. Marketed Devices

z3D Contrast Acuity Version 2.1 is substantially equivalent to the legally marketed predicate devices listed below:

Model:	MedIQ
Manufacturer:	Clario Medical Imagining, Inc.
510(k) Number:	K052963

Model:	CADstream Version 4.0
Manufacturer:	Confirma, Inc.
510(k) Number:	K043216

4. Device Description

z3D Contrast acuity (z3D) Version 2.1 is a software package designed to assist the radiologist in interpretation of multi-modality, digital radiology images, including dynamic CT and MR image data sets. The software applies standard 2D and 3D image processing techniques on a pixel-by-pixel basis to analyze grayscale data and perform visual enhancement of user-selected images. The software may be applied to image subtractions, reformatted images, multiplanar reformats, and Maximum Intensity Projections (MIP). Single or multi-slice data sets may be used as input.

The software consists of several modes that can be enabled or disabled depending upon the specific configuration purchased/implemented. These modes include 2D image review, 2D mass morphology, 3D mass characterization.

The results of the analysis are displayed as a surface map, parametric map, Maximum Intensity Projection (MIP), subtraction, registered subtraction, or 3D display that enhances visualization of pixel intensity data provided by the image. The results may be displayed in grayscale enhancement or as a color overlay. The software includes standard workflow tools that allow the radiologist to manipulate, rotate and fly-through images for enhanced visualization of the digital output. Additionally, the software package allows the radiologist to visually inspect time sensitive contrast agent intensity curves and to make mass measurements.

The software application consists of proprietary software developed by Clario and is a Windows 2000/XP, DICOM-compatible platform. The software is designed to be distributed as a plug-in for OEM imaging systems, PACS, workstations, or embedded in software applications cleared for use in medical imaging.

The z3D user interface is designed to follow typical workflow patterns to process, review, and analyze digital images.

5. Indications for Use

z3D Contrast Acuity (z3D) version 2.1 is a post-processing, productivity software package designed to assist radiologists in the analysis of dynamic CT and MR images. The software provides image display, supplemental information and visual enhancement of time/intensity changes extracted from CT and MR temporal datasets. Single or multi-slice datasets, using standard acquisition protocols, are used for input.

changes extracted from CT and MR temporal data sets. The results may be displayed as either a grayscale enhancement or a color overlay on the selected image.

z3D may perform additional functions to aid in the analysis and viewing of dynamic studies, including registration of serial MR and CT acquisitions, labeling of tissue types based upon user specified enhancement characteristics, visualization and quantification of lesion morphology in 3D, segmentation of tissues, multiplanar and oblique reformats, maximum intensity projections, image averaging, subtraction and blinking of images acquired at different time points to help visualize enhancement.

z3D also may be used to perform post-processing analysis of multi-modality, digital images, including MR, CT, X-Ray, PET, and Nuclear Medicine images. The software analysis tools may be applied to image subtractions, reformatted images, multiplanar reformats, and maximum intensity projections.

The software package includes tools to allow the radiologist to manipulate and fly-through images for enhanced visualization.

When interpreted by a skilled physician, this device provides information that may be useful in screening and diagnosis. Patient management decisions should not be made based solely on the results of z3D analysis. The z3D software is contraindicated for automated sole interpretation of digital mammography images.

6. Comparison with Predicate Devices

Clario Medical Imaging, Inc. believes that the product described in this Submission is substantially equivalent to a combination of the MedIQ/K052963 and CADstream/K043216 devices.

z3D and the cited predicate devices are designed to assist radiologists in analyzing pixel intensity data from multi-modality, digital images and performing post-processing analysis of selected images using standard software techniques. The output of these software packages is intended to provide supplemental information and enhanced visual analysis of the digital images selected by the user for processing.

The Clario software product, MedIQ, and the Confirma software product, CADstream, perform post-processing analysis of dynamic CT and/or MR images to enhance the radiologist's visual interpretation of time/intensity changes observed in temporal data sets obtained during the administration

The Clario software product, MedIQ, and the Confirma software product, CADstream, perform post-processing analysis of dynamic CT and/or MR images to enhance the radiologist's visual interpretation of time/intensity changes observed in temporal data sets obtained during the administration of contrast agents. The output is displayed as curves or color parametric images from user-specified processing of algorithms.

The Clario software product MedIQ provides functional features that are equivalent to z3D, allowing the user to view and manipulate images in 3D in real time, and to provide 3D surface shading of selected images.

The Confirma software product, CADstream, provides the functional feature that allows the user to make measurements on images.

The cited predicate devices allow easy selection, review, processing, archiving, printing and media interchange of multi-modality images from a variety of diagnostic imaging systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2008

Mr. Chris Wood
CEO
Clario Medical Imaging, Inc.
1924 1st Avenue, Suite 4W
SEATTLE WA 98101

Re: K080196
Trade/Device Name: z3D Contrast Acuity
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 12, 2008
Received: August 14, 2008

Dear Mr. Wood:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: To be assigned by FDA

Device Name: z3D Contrast Acuity

z3D Contrast Acuity (z3D) version 2.1 is a post-processing, productivity software package designed to assist radiologists in the analysis of dynamic CT and MR images. The software provides image display, supplemental information and visual enhancement of time/intensity changes extracted from CT and MR temporal datasets. Single or multi-slice datasets, using standard acquisition protocols, are used for input.

The software displays the temporal variation in dynamic data as a surface map that enhances visualization of pixel intensity and time/intensity changes extracted from CT and MR temporal data sets. The results may be displayed as either a grayscale enhancement or a color overlay on the selected image.

z3D may perform additional functions to aid in the analysis and viewing of dynamic studies, including registration of serial MR and CT acquisitions, labeling of tissue types based upon user specified enhancement characteristics, visualization and quantification of lesion morphology in 3D, segmentation of tissues, multiplanar and oblique reformats, maximum intensity projections, image averaging, subtraction and blinking of images acquired at different time points to help visualize enhancement.

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Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080196